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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR      | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/973,088      | 10/10/2001  | Marie B. Connett-Porceddu | 2411-110            | 4800             |

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ROTHWELL, FIGG, ERNST & MANBECK, P.C.  
1425 K STREET, N.W.  
SUITE 800  
WASHINGTON, DC 20005

EXAMINER

BAUM, STUART F

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1638

DATE MAILED: 05/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |   |  |
|------------------------------|-------------------------------|---|--|
| <b>Office Action Summary</b> | Application No.<br>09/973,088 | Applicant(s)<br>CONNETT-PORCEDDU ET AL. |  |
|                              | Examiner<br>Stuart Baum       | Art Unit<br>1638                        |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 63-81 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Applicant claims a transformed embryogenic culture and a transformed pine plant of the genus *Pinus* subgenus *Pinus* both culture and plant were prepared by the claimed methods. Applicant has not described the DNA that was transformed into said plant or culture.

The Applicant does not identify structural, genotypic, or phenotypic features unique to the transformed plants or embryogenic cultures. The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. Since the genetic material has not been described by genotype, phenotype, specific structural features or by specific function, the specification fails to provide an adequate written description to support the generic claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 12-16, 20, 22, 25-43, 46-48, 52-54, 58, 60, 63-81 rejected under 35

U.S.C. 102(b) as being anticipated by Levee et al (1999, Molecular Breeding 5(5):429-440).

The claims are drawn to a method for regenerating transgenic plants of pine of the genus *Pinus* comprising subjecting pine cells to *Agrobacterium* infection, killing, removing or rendering the *Agrobacterium* harmless so as not to damage the growing cells, minimizing damage to cells during and subsequent to *Agrobacterium* treatment, rapidly transforming cells, culturing transformed cells to produce transgenic somatic embryos and growing somatic embryos into transgenic plants. The claims are also drawn to a method comprising a support membrane onto which the *Pinus* cells are placed and the membrane is used to move the cells from the transformation stage of the process, to the step in which the *Agrobacterium* is killed or rendered harmless, to the step of growing the embryogenic cells into somatic embryos.

Levee et al teach a method of stable transformation of *Pinus strobes* after cocultivation of embryogenic tissues with *Agrobacterium* in which a support membrane is used. The method of Levee et al involves subculturing embryogenic tissues in liquid medium where they are suspended in said medium. *Agrobacterium* cells are grown to a particular titer and then equal volumes of the two solutions are mixed. For the cocultivation step, the mixture is spread on Whatman filter paper and the liquid medium is removed by a low-pressure pulse using a Buchner

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funnel. The filter paper with *Agrobacterium* and *Pinus* cells is placed in a Petri dish containing a semi solid medium. Embryogenic tissues are cocultivated with *Agrobacterium* for two days. After cocultivation, the embryogenic tissue is washed in 100 ml of water to remove *Agrobacterium* and then with tetracycline to kill the bacteria. The cells are collected onto a support membrane which is placed onto a medium containing a chemical toxic to the bacteria but which allows the embryogenic cells to grow. After a week, the support membrane with embryogenic cells is transferred onto a selective medium (containing Kanamycin) to select for transformed *Pinus* cells. Kanamycin-resistant cell lines are then isolated and allowed to grow into somatic embryos and finally into plants (page 431, left column, under “transformation procedure”).

The method of Levee et al “minimizes damage to cells” by growing them in liquid culture and allowing them to grow on a “support membrane” which facilitates the “fast selection” and movement of cells to an environment for efficient “*Agrobacterium* transformation” and continued growth to produce “transgenic somatic embryos”. Rinsing and recovering of cells is accomplished through the use of a liquid suspension culture either using water or some type of medium and then collecting cells on a “support membrane”. Transformed cells are supported on a “support membrane” which is used to transfer “embryogenic” cells from one “gelled medium” containing a “selection agent” to another “gelled medium” containing a chemical that inhibits and/or kills (i.e. “eradicant”) the *Agrobacterium*. Furthermore, the eradication of *Agrobacterium* would not confer any characteristics on the transformed *Pinus* that would differentiate it from the transformed *Pinus* taught by Levee et al. This method produces

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transformed pine plants as claimed by the Applicants and hence Levee et al anticipate the claimed method.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levee et al (1999, Molecular Breeding 5(5):429-440).

The claims are drawn to a method for regenerating transgenic plants of pine of the genus *Pinus* comprising subjecting pine cells to *Agrobacterium* infection, killing, removing or rendering the *Agrobacterium* harmless so as not to damage the growing cells, minimizing damage to cells during and subsequent to *Agrobacterium* treatment, rapidly transforming cells, culturing transformed cells to produce transgenic somatic embryos and growing somatic embryos into transgenic plants. The claims are also drawn to a method comprising a support membrane onto which the *Pinus* cells are placed and the membrane is used to move the cells from the transformation stage of the process, to the step in which the *Agrobacterium* is killed or rendered harmless, to the step of growing the embryogenic cells into somatic embryos.

Levee et al teach a method of stable transformation of *Pinus strobes* after cocultivation of embryogenic tissues with *Agrobacterium* in which a support membrane is used. The method of Levee et al involves subculturing embryogenic tissues in liquid medium where they are suspended in said medium. *Agrobacterium* cells are grown to a particular titer and then equal

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volumes of the two solutions are mixed. For the cocultivation step, the mixture is spread on Whatman filter paper and the liquid medium is removed by a low-pressure pulse using a Buchner funnel. The filter paper with *Agrobacterium* and *Pinus* cells is placed in a Petri dish containing a semi solid medium. Embryogenic tissues are cocultivated with *Agrobacterium* for two days. After cocultivation, the embryogenic tissue is washed in 100 ml of water to remove *Agrobacterium* and then with tetracycline to kill the bacteria. The cells are collected onto a support membrane which is placed onto a medium containing a chemical toxic to the bacteria but which allows the embryogenic cells to grow. After a week, the support membrane with embryogenic cells is transferred onto a selective medium (containing Kanamycin) to select for transformed *Pinus* cells. Kanamycin-resistant cell lines are then isolated and allowed to grow into somatic embryos and finally into plants (page 431, left column, under “transformation procedure”).

Levee et al does not teach varying the time the cells are washed to between half an hour to overnight, using a support membrane made from polyester, polypropylene or liquid permeable fluoropolymer fabric, a filter paper absorbed with a selection agent, eradicating *Agrobacterium* after the transformation procedure, a filter paper absorbed with an eradicant, placing the support membrane over a thin film of liquid medium or over filter paper with liquid medium absorbed therein, and placing the selection agent in a thin film of liquid medium

Given the recognition of those of ordinary skill in the art of the value of producing a transformed pine plant comprising cocultivating *Agrobacterium* with embryogenic pine tissue in a liquid medium and then harvesting cells onto a support membrane which is used to transfer the cell to different media for the purpose of growing pine cells, eradicating *Agrobacterium* and

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selecting transformed embryogenic tissue, as taught by Levee et al, it would have been obvious to optimize this method by optimization of process parameters that would not confer patentable distinction on the claimed invention.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, 5, 6, 20, 25, 27-30, 32-38, and 52 and all claims dependent thereon, are indefinite in the recitation “subjecting” or “subjected”. This term does not explicitly describe how the pine cells are being infected by *Agrobacterium*.

Claim 1, 2, 4, 25, 26, 31, and 39 and all claims dependent thereon, are indefinite in the recitation “minimizing damage” or “minimized”. It is not clear from the Applicants description, what damage is trying to be minimized. Applicant needs to specifically state the damage that is being minimized.

Claim 1, 12, and 25 and all claims dependent thereon, are indefinite in the recitation “rapidly selecting”. This term does not describe how quickly (i.e. hours, days, weeks) the cells



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must be selected and it does not describe how the cells are being selected. Are they selected by a particular phenotype or marker gene?

Claim 1 and 25 and all claims dependent thereon, are indefinite in the recitation “germinating”. This term is used in regards to seeds. Applicant needs to describe how the somatic embryos are subsequently grown to produce a growing plant.

Claim 2, 4, and 25 and all claims dependent thereon, are indefinite in the recitation “damage”. Applicant has not described the parameters that constitute a damaged cell.

Claim 2, 26, and 39 and all claims dependent thereon, are indefinite in the recitation “resuspending”. Resuspending implies that the cells are already suspended in a described medium. Suspending the cells has not been previously described.

Claim 2, and 26 and all claims dependent thereon, are indefinite in the recitation “agitating”. Applicant has not explicitly stated how one agitates cells in a liquid wash medium.

Claims 2, 4, 26, and 31 and all claims dependent thereon, are indefinite because it is unclear if the method comprises all of steps (a), (b) and (c), or if only one of these steps is required. Amendment of the claims by insertion of “and” or “or” at the end of step (b) would overcome the rejection.

Claim 2, 4, 31, and 39 are indefinite in the recitation “recovering washed, transformed cells with minimal damage”. Applicant has not described how one determines that a cell has been transformed, and how one recovers a cell and what damage is trying to be minimized and how one minimizes the damage.

Claim 3, 5, 6, 11, 12, 14, 18, 24, 27, 29, 30, 32-37, 39, 40, 45-48, 51, 52, 54, 57, 58, and 62 and all claims dependent thereon, are indefinite, vague and unclear in the recitation “support

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membrane”, since it is unclear what is supported. Therefore, it is unclear what would constitute a support membrane in the claimed method.

Claim 4, and 31 and all claims dependent thereon, are indefinite in the recitation “rinsing”. Applicant needs to describe how the cells are rinsed, since it is unclear what is washed away in this process.

Claim 2, 4, 20, 26, 29, 30, 31, 35, 36, 38, 39, and 58 and all claims dependent thereon, are indefinite in the recitation “recovering with minimal damage”. Applicant needs to describe how the cells are being gathered.

Claim 7, and 41 and all claims dependent thereon, are indefinite in the recitation “contamination is no longer detectable”. It is not clear how the *Agrobacterium* are contaminating the cells given that the transformation method using *Agrobacterium*. It is also not clear how one determines when the contamination is no longer detectable. How does one assay for contaminating *Agrobacterium*?

Claim 9, and 43 and all claims dependent thereon, are indefinite in the recitation “duration sufficient”. It is not clear from the claim language how one determines a sufficient amount of time. Is there an assay, marker, color or recognizable phenotype that assists the experimenter in determining an appropriate amount of time?

Claim 9 and all claims dependent thereon, is indefinite in the recitation “interfering”. How does one know if the growth has been interfered with? Applicant needs to explicitly state the amount of time the cells are to be washed.

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Claim 12, and 25 and all claims dependent thereon, are indefinite in the recitation “rapid”. This is a relative term and Applicant does not provide a reference. Applicant needs to explicitly state the amount of time.

Claim 19 and all claims dependent thereon, is indefinite in the recitation “eradication of *Agrobacterium*”. As written, this term implies that Applicant is removing *Agrobacterium* from the face of the Earth. Applicant is advised to amend the claim to read on the *Agrobacterium* that is used in the claimed method.

Claim 21, 49, and 59 and all claims dependent thereon, are indefinite in the recitation “thin”. This is a relative term and Applicant needs to explicitly state the dimensions of the layer.

Claim 22, 49, and 59 and all claims dependent thereon, are indefinite in the recitation “film”. What constitutes a film of gelled medium? Applicant needs to explicitly define this term.

Claim 25 and all claims dependent thereon, is indefinite in the recitation “eradicating *Agrobacterium*” and “*Agrobacterium* eradication”. As written, this term implies that Applicant is removing *Agrobacterium* from the face of the Earth. Applicant is advised to amend the claim to read on the *Agrobacterium* that is used in the claimed method.

Claim 29, and 38 and all claims dependent thereon, are indefinite in the recitation “said eradication” as there is no antecedent basis for this term.

Claim 29-31, 35, 36, 39, and 58 and all claims dependent thereon, are indefinite in the recitation “recovering”. Applicant needs to state how the cells are being gathered or collected.

Claim 39 and all claims dependent thereon, is indefinite in the recitation “minimal physical damage”. Minimal is a relative term and Applicant needs to explicitly state how the

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cells are recovered. In addition, it has not been defined what constitutes physical damage. How is one to evaluate the extent of the damage to the cells?

Claim 41 and all claims dependent thereon, is indefinite in the recitation "*Agrobacterium* contamination is no longer detectable". How does one assay for the presence of *Agrobacterium*? Applicant needs to explicitly state how one detects *Agrobacterium*.

Claim 47 and all claims dependent thereon, is indefinite, vague and unclear in the recitation "culture components". Applicant needs to explicitly state what are the components that make-up the culture.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the legal analyst, Kim Davis, whose telephone number is (703) 305-3015.

Stuart Baum Ph.D.

May 10, 2002

ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1800

